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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,811	11/25/2003	Charles Hensley	33205.0217	8179

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,811	HENSLEY ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 11-42 are pending in this application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 11, 13-20, 22 and 41, drawn to composition for delivering an active substance to a nasal membrane, wherein the active substance is zinc, and method of treating a cold with the composition, wherein there is no additional viscosity claim requirement, classified in class 424, subclasses 641-642, class 514, subclass 494.

II. Claims 11-16, 19-20, 22 and 41, drawn to composition for delivering an active substance to a nasal membrane, wherein the active substance is a non-zinc homeopathic active substance, and method of treating a cold with the composition, wherein there is no additional viscosity claim requirement, classified in multiple subclasses in classes 424 and 514 depending on the specific identity of the active substance.

III. Claims 11, 13-16, 19-20, 22 and 41, drawn to composition for delivering an active substance to a nasal membrane, wherein the active substance is a non-zinc, non-homeopathic active substance, and method of treating a cold with the composition, wherein there is no additional viscosity claim requirement, classified in multiple subclasses in classes 424 and 514 depending on the specific identity of the active substance.

IV. Claims 21 and 23-27, 29, 31-34, 36-39, drawn to composition for delivering an active substance to a nasal membrane and method of administering an effective amount of an active substance, wherein the active substance is zinc and the composition has a viscosity of about 2,500-40,000 cp.

V. Claims 21, 23-26, 29-30, 33-34, 36, 39, drawn to composition for delivering an active substance to a nasal membrane and method of administering an effective amount of an active substance, wherein (i) the active substance is a non-zinc homeopathic compound, and (ii) the composition has a viscosity of about 2,500-40,000 cp.

VI. Claims 21, 23-26, 29, 33-35, 36, 39, drawn to composition for delivering an active substance to a nasal membrane, wherein (i) the active substance is a decongestant that is neither zinc nor a homeopathic compound, and (ii) the composition has a viscosity of about 2,500-40,000 cp.

VII. Claims 21, 23-26, 29, 33-34, 36, 39, drawn to composition for delivering an active substance to a nasal membrane, wherein (i) the active substance is not zinc, not a homeopathic compound and not a decongestant, and (ii) the composition has a viscosity of about 2,500-40,000 cp.

VIII. Claim 40, drawn to composition for reducing the severity and duration of a cold, the composition comprising about: 0.000001-5 wt% thickener, 0.05-5 wt% glycerin, 0.0000001-10 wt% active substance, 0.000001-5 wt% salt, wherein the viscosity of the composition is about 2,500-40,000 cp.

IX. Claim 42, drawn to sprayable composition comprising an active substance, carrier comprising a thickening agent, wherein the composition has a viscosity greater than about 2,500 cp and can be applied by spraying.

In the event that applicant were to elect group II, III, V, VI, VII, VIII or IX, applicant is further required to elect for examination purposes a patentably distinct single disclosed species of the active substance, such as for example NaCl for group II. Applicant is advised that should claims 40 or 42 be further amended to add dependent claims like those for independent claim 11, similar further restriction may be necessary.

The nine inventions as set forth above are distinct by virtue of their distinct composition makeup. Groups I-III are distinct over groups IV-VII because groups IV-VII require viscosity of 2500-40000 cp, whereas groups I-III have no such viscosity requirements. Group VIII composition is distinct over the other compositions due to the specifics of the ingredients and the presence of salt, glycerin and another thickener. Group IX composition is specified as sprayable, with a viscosity greater than 2500 cp, with no upper limit.

The claims as presently pending cannot all be searched and examined together in one application. Even a search of just one invention would be of serious burden, due to the extensive breadth of claim scope and the extensive collection of prior art documents. The claims basically read on every known active pharmaceutical substance, homeopathic or otherwise, formulated with conventional carriers such as glycerin, carbohydrate, gum, or cellulose. To properly search all the claims the Examiner is faced with reviewing all liquid formulations of any conceivable active substance that could be delivered nasally. This is not possible in one application without placing undue burden on the Examiner. Even when limited to zinc active substance, there would be undue burden on the Examiner in having to search and examine more than one invention group because of the complexity of claim search/examination vis-à-vis prior art review. Viscosity feature is something that is not readily discernible in most prior art compositions that do not expressly provide such viscosity parameters even when the viscosity is inherently within the ambit of claim features, so review of relevant prior art related to viscosity feature is extremely challenging. Add to that the various different features such as salt, non zinc active substances, various different carriers and thickening agents, sprayable feature, viscosity that is only recited in terms of a lower limit of 2500 cp instead of 2500-40000 cp, and the search and examination of more than one invention group cannot be made without placing an undue burden on the Examiner.

For reasons of distinctness and undue burden, the restriction requirement as set forth above is deemed to be proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

It is noted that this application is stated to be a CON of 09/145,042 in the Application Transmittal form. However, the declaration also claims benefit of 09/603,864. Applicant is requested to amend the specification, with updated patent numbers if appropriate, to properly recite the accurate claim of benefit of earlier filed applications.

It is also noted that the inventors of this application are different from the inventors of the alleged CON parent, 09/145,042. Applicant must follow proper procedures to remove inventors in subsequently filed CON cases. MPEP 201.06(c).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600